K071957

510(k) Summary for the Pinnacle™ Pelvic Floor Repair Mesh

A. Sponsor

Boston Scientific Corporation
Urology and Gynecology Division
100 Boston Scientific Way
Marlborough, MA 01756

NOV 0 8 2007

B. Contact

Michelle M. Berry
Senior, Regulatory Affairs Specialist
508-683-4941
or
Donna Gardner
Director, Regulatory Affairs
508-683-4398

C. Device Name

Tradename: Pinnacle™ Pelvic Floor Repair Kits
Common/usual name: Surgical Mesh
Classification Name: FTL – Mesh, Surgical, Polymeric
21 CFR 878.3300, Class II

D. Predicate Device(s)

Tradename: Polyform Synthetic Mesh
Common/usual name: Surgical Mesh
Classification Name: OTP - Mesh, Surgical, Polymeric
21 CFR 878.3300, Class II
Premarket Notification: Proxy Biomedical, Ltd., K051245

E. Device Description

The proposed device is a sterile, single use device, consisting of a synthetic mesh assembly and needle holder. The mesh assembly consists of a polypropylene knitted mesh body with integrated legs that are protected by disposable polymer sleeves. At the distal end of the disposable polymer sleeve is a lead with needle designed for use with the currently legally marketed Capio™ Open Access Suture Capturing Device. The disposable lead was designed to facilitate the passage of the proposed mesh through bodily tissues for placement. The proposed mesh will be offered in three mesh models: Total, Anterior/Apical and Posterior designed for performing total vaginal repair, anterior vaginal defects and posterior and/or apical vaginal vault defects respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Michelle M. Berry
Senior Regulatory Affairs Specialist
Boston Scientific Corporation
100 Boston Scientific Way
MARLBOROUGH MA 01752

SEP 28 2012

Re: K071957
Trade/Device Name: Undetermined
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTP
Dated: October 3, 2007
Received: October 4, 2007

Dear Ms. Berry:

This letter corrects our substantially equivalent letter of November 8, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if Known): K071957

Device Name: Undetermined

Indications For Use:

The Pinnacle™ Pelvic Floor Repair Kits are indicated for tissue reinforcement and stabilization of fascial structures of the pelvic floor for vaginal wall prolapse, where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

Prescription Use __X____ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071957